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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/998,716 | 11/30/2001 | Alex J. Harvey | AVI 019 | 7210 |

7590 06/18/2004
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Atlanta, GA 30357-0037

EXAMINER

SULLIVAN, DANIEL M

| ART UNIT | PAPER NUMBER |
|----------|--------------|
|----------|--------------|

1636

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

34.

Office Action Summary**Application No.**

09/998,716

Applicant(s)

HARVEY ET AL.

Examiner

Daniel M Sullivan

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 April 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,4-7,10-18,21-34 and 36-53 is/are pending in the application.
- 4a) Of the above claim(s) 38-50 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,4-7,10-18,21-34,36,37 and 51-53 is/are rejected.
- 7) ☒ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This Office Action is a reply to the Paper filed 12 April 2004 in reply to the Non-Final Office Action mailed 16 January 2004. Claims 1-37 were considered and claims 38-50 were withdrawn from consideration in the 16 January Office Action. Claims 8, 9, 19, 20 and 35 were canceled, claims 1, 10, 12, 21, 23, 27-34, 36 and 37 were amended and claims 51-53 were added in the 12 April Paper. Claims 1, 4-7, 10-18, 21-34 and 36-53 are pending and claims 1, 4-7, 10-18, 21-34, 36, 37 and 51-53 are under consideration.

Response to Amendment

Rejection of claims 8, 9, 19, 20 and 35 is rendered moot by cancellation thereof.

Double Patenting

Claims 7 and 14 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 2 of either one of copending Applications No. 10/463,980 or 10/351,196.

In the Remarks filed 12 April 2004, Applicant agrees to consider the filing of a terminal disclaimer once the scope of allowed claims of the instant application and the relevant claim 2 of application serial numbers 10/463,908 or 10/351,196 are known. This is acknowledged; however, the rejection will stand until such time as a terminal disclaimer is filed or the claims are amended such that they are patentably distinct.

Specification

Objection to the disclosure as containing informalities is withdrawn.

Claim Objections

Objection to claims 30-34, 36 and 37 as containing informalities is withdrawn.

Claim Rejections - 35 USC § 101

Rejection of claims 30 and 36-37 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter is withdrawn in view of the amendments to the claims.

Claim Rejections - 35 USC § 112

Claims 1, 4-7, 10-18, 21-34, 36, 37 stand rejected and claims 51-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for reasons of record and herein below in the response to arguments.

Rejection of claims 5 and 6 under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter is withdrawn. One of ordinary skill in the art would reasonably expect that a nucleic acid comprising a sequence 95% and 99% identical the disclosed SEQ ID NO: 26 would be operable as a promoter.

Claims 1, 4, 7, 10-18, 21-34, 36 and 37 stand rejected and claims 51-53 are rejected under 35 U.S.C. 112, first paragraph, as lacking enablement for the full scope of the claimed subject matter for reasons of record and herein below in the response to arguments.

Rejection of claims 1-6, 10, 12, 21, 23 and 27-29 under 35 U.S.C. 112, second paragraph, as indefinite is withdrawn in view of the amendments to the claims.

Response to Arguments

Claims 1, 4-7, 10-18, 21-34, 36, 37 and 51-53 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because a skilled artisan would not have viewed the teachings of the specification as providing adequate written description for the broad class of nucleic acids encompassed by the ovomucoid gene expression control regions of the claims. The Office Action states, “only the described nucleic acid comprising the sequence set forth as SEQ ID NO: 26 meets the written description provision of 35 U.S.C. §112, first paragraph.”

In reply, Applicant states, “[c]laims 2, 3, 8, 9, 19 and 20 are herein canceled. This rejection is, therefore, now rendered moot and should be withdrawn.”

Applicant’s arguments have been fully considered but are not deemed persuasive because the cancellation of claims 2, 3, 8, 9, 19 and 20 does not overcome the rejection of the presently pending claims. As discussed in the previous Office Action the specification teaches that the ovomucoid gene expression control region is a region located 5’ to the transcription start site of a chicken ovomucoid gene and there is no description of variants of the ovomucoid gene expression control region in chicken other than that described by SEQ ID NO: 26.

Furthermore, the “portion” of a nucleic acid comprising SEQ ID NO: 26 recited in amended claims 1, 10 and 21 encompasses subject matter beyond what is described in the specification. Specifically, a nucleic acid comprising SEQ ID NO: 26 contains undefined

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sequence as well as SEQ ID NO: 26. Thus, a fragment of a nucleic acid comprising SEQ ID NO: 26 need not comprise SEQ ID NO: 26 at all because the fragment could consist of the undefined sequence. For example, a fragment of a nucleic acid comprising SEQ ID NO: 26 encompasses any fragment of a chromosome or vector that contains SEQ ID NO: 26. Clearly, these fragments are not adequately described in the instant disclosure.

Claims 1, 4, 7, 10-18, 21-34, 36, 37 and 51-53 are rejected under 35 U.S.C. 112, first paragraph, as lacking enablement for an isolated nucleic acid beyond the scope of a nucleic acid comprising the sequence set forth as SEQ ID NO: 26.

In response, Applicant states, “claims 1, 10 and 21 are amended to delete the phrase ‘or degenerate variants thereof’” and requests that the rejection be withdrawn.

This argument has been fully considered but is not deemed persuasive. First, as discussed herein above, the “portion” of a nucleic acid comprising SEQ ID NO: 26 encompasses essentially unlimited sequence. The specification is clearly not enabling for such scope.

Furthermore, although the specification is enabling for isolated nucleic acids comprising fragments of SEQ ID NO: 26, which can be used as nucleic acid probes (contemplated on page 23 of the specification), it is not enabling for nucleic acids operably linked to a portion of SEQ ID NO: 26 or a nucleic acid comprising only 75%, 80%, 85% or 90% identity to SEQ ID NO: 26, cells comprising isolated nucleic acids comprising a portion of SEQ ID NO: 26 or 75% identity to SEQ ID NO: 26 or methods of using a portion of SEQ ID NO: 26 or a nucleic acid comprising only 75%, 80%, 85% or 90% identity to SEQ ID NO: 26 to express a protein.

As stated in the 16 January Office Action, “the requisite components that provide useful function of an ovomucoid promoter are undefined and no guidance is provided as to how the disclosed nucleic acid sequence might be varied such that the nucleic acid can still be used for the expression of an operably linked heterologous nucleic acid insert in a transfected avian cell short of blind trial and error experimentation” (first full paragraph on page 9). For the reasons set forth in the previous Office Action, making the full scope of the fragments of SEQ ID NO: 26 that could be operably linked to a heterologous nucleic acid or that would be useful to express a protein would require undue trial and error experimentation.

Therefore, for reasons of record and herein above, the claims stand rejected under 35 U.S.C. §112, first paragraph, as lacking enablement for the full scope of the claimed subject matter.

New Grounds Necessitated by Amendment

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Entrez Nucleotide Database entry Accession No. M16141 (published 1994).

The M16141 entry discloses a sequence that is 100% identical to the instant SEQ ID NO: 26 from nucleotide 44 to 196 (see especially nucleotides 53 to 206). Thus, the M16141 entry anticipates the nucleic acid comprising a portion of SEQ ID NO: 26 claimed in claim 1.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Daniel M Sullivan whose telephone number is 571-272-0779. The examiner can normally be reached on Monday through Thursday 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

DMS

Anne-Marie Falk
ANNE-MARIE FALK, PH.D
PRIMARY EXAMINER